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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MCINTOSH III, TRAVISS C	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,548	LIU ET AL.	
	Examiner	Art Unit	
	Traviss C McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38,42,43,58,59,73,79,82,89-91,99 and 113-203* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38,42,43,58,59,73,79,82,89-91,99 and 113-203* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed February 20, 2004 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 9, 42-43, and 116-122 have been amended.

Claims 39-41, 44-57, 60-72, 74-78, 80-81, 83-88, 92-98, and 100-112 stand as being canceled.

Claims 141-203 have been added.

Remarks drawn to rejections of Office Action mailed November 18, 2003 include:

Claim objections: which have been overcome by applicant's amendments and have been withdrawn, and even though applicants state on the record that the inventions of independent claims are directed to patentably distinct subject matter, the examiner has not restricted the case.

112 2nd paragraph rejections: which have been overcome in part by applicant's amendments and have been withdrawn.

102(b) rejection: which has been overcome by applicant's arguments and has been withdrawn.

103(a) rejections: which have been overcome by applicant's arguments and has been withdrawn.

An action on the merits of claims 1-38, 42-43, 58-59, 73, 79, 82, 89-91, 99, and 113-203 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Specification

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). In the instant case, applicants state on page 50, lines 14-15 of the specification that "all references, patents and patent publications that are recited in this application are incorporated in their entirety herein by reference", however, applicant's are relying on various references to teach essential material, such as the biotechnology derived heparin of claim 6 and chemically modified heparin of claim 7 wherein the specification defines the same on page 21 as: "the term biotechnological heparin encompasses heparin that is prepared from natural sources of polysaccharides which have been chemically modified and is described in Razi et a1., Bioche. J. 1995 Jul 15;309 (Pt 2): 465-72. Chemically modified heparin is described in Yates et al., Carbohydrate Res (1996) Nov 20;294:15-27, and is known to those of skill in the art. Synthetic heparin is well known to those

of skill in the art and is described in Petitou, M. et al., Bioorg Med Chem Lett. (1999) Apr 19;9(8):1161-6 and Vlodavsky et al., Int. J. Cancer, 1999, 83:424-431".

Claim Objections

Applicant is advised that should claims 113-129 be found allowable, claims 141-157 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 141-157 are identical to claims 113-129 respectively.

Likewise, applicant is advised that should claims 130-134 be found allowable, claims 171-175 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Claims 171-175 are identical to claims 130-134 respectively.

Additionally, applicant is advised that should claims 135-140 be found allowable, claims 178-183 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Claims 178-183 are identical to claims 135-140 respectively.

Claim Rejections - 35 USC § 112

Claims 6-10, 32, 121, 123, 149, 151, 162, 185, and 196 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. These claims all comprise various "biotechnology derived heparin", "chemically modified heparin", "heparin analogue", "AT-III binding saccharides", or "unfractionated heparin preparations". Applicants have not adequately described how to make these products, and have relied on various references which they improperly attempted to incorporate by reference to teach how to make said products. Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. ***In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973).***

Claims 17-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. All of these claims intend to limit the subject to be treated as subjects which are "at risk" of obtaining various disorders, but the specification does not disclose any methods of determining if a subject is "at risk of atherosclerosis" or "at risk of an inflammatory disorder". The specification lacks an adequate written description of the risk factors associated with all of the various disorders, and thus the examiner concludes that applicant's were not in possession of the claimed invention at the time of filing.

Claims 1-38, 58-59, 73, 82, 89-91, 113-115, 121, 123, 126-127, 130-143, 149, 151, 154-155, 158-175, 178-190, and 196-198 are rejected under 35 U.S.C. 112, second paragraph, as

being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claim 1 for being indefinite wherein the claim is drawn to "a method for producing a therapeutic effect, comprising: administering to a pulmonary tissue of a subject an unformulated dry polysaccharide particle in an **effective amount** for producing a therapeutic effect..." is maintained for reasons of record. The term "effective amount" is indefinite where the claim fails to state the function which is to be rendered effective. See ***In re Frederiksen, 102 USPQ 35 (CCPA 1954).*** Applicants argue that the effective amount is definite as it is one which produces a therapeutic effect. However, the claim is silent as to what therapeutic effect is produced and it is noted that a "therapeutic effect" is not a function which can be rendered effective. Moreover, applicants arguments that the specification sufficiently defines the term are noted, however, in the examination process it is proper to use the specification to interpret what applicant intends by a word or phrase recited in the claims, but it is **not** proper to read these limitations appearing in the specification into the claim when these limitations are not recited in the claim. See ***In re Paulsen,* 30 F. 3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994)**.

The rejection of the claims for the use of "low molecular weight heparin" is withdrawn. The examiner agrees with applicants and believes that one of skill in the art would understand and recognize the metes and bounds of the claim as low molecular weight heparins are known in the art.

The recitation in a dependent claim of the source of an active agent to be used in a method from which said claim depends, wherein the "source of the active agent" does not result in a patentably distinguishable methodological and manipulative difference in how said active

agent's source impacts the method from which it depends, renders the claim(s) in which it occurs and which depend therefrom indefinite for failing to distinctly articulate how such a recitation further limits the method from which said dependent claim(s) applicant regards as the invention. In the instant case, claim 6 provides that "wherein the heparin is a biotechnology derived heparin", and it is unclear how the method of making the heparin will effect the method of using the heparin, as the molecule heparin is heparin, regardless of where it comes from. Applicants argue that the claim narrows claim previous claim (claim 5), however, claim 6 is not dependent from claim 5, but from claim 3. The examiner is unclear how the source of the heparin would affect the method of its use.

The rejection of the phrase, "a chemically modified heparin" as being indefinite is maintained for reasons of record. The claim does not set forth how the heparin is modified, and to what extent the heparin is modified. Heparin is an art known compound which can be modified in a multitude of ways. In the absence of the identity of moieties which are intended to modify the art recognized chemical core, described structurally or by chemical name, the identity of "a modified heparin" would be difficult to ascertain. In the absence of said moieties, the claims containing the term "modified" are not described sufficiently to distinctly point out that which applicant intends as the invention. Applicants contend that one of skill in the art would recognize what a "chemically modified heparin" is and that they are not claiming the modified heparins themselves, but methods of their use. However, how could someone use something if they are not able to determine what it is? Moreover, heparin can be modified to any number of various compounds with divergent properties and activities. Heparin can be chemically modified to water. Heparin can be chemically modified to D-glucosamine. Heparin can be modified to D-

glucosamine attached to a steroid molecule. The metes and bounds of the claim cannot be determined by one of skill in the art and therefor, the claim is indefinite.

Claim 31 recites the limitation "the angiogenic disorder" in the first line. There is insufficient antecedent basis for this limitation in the claim. It appears that claim 31 should depend from claim 30, not claim 2.

The rejection of claim 32 as being indefinite wherein the claim provides that the polysaccharide is optionally a pectin "derivative" is maintained for reasons of record. In the absence of the identity of moieties intended to modify an art recognized chemical core, described structurally or by chemical name, the identity of a "derivative" would be difficult to ascertain. In the absence of said moieties, the claims containing the term "derivative" are not described particularly sufficiently to distinctly point out that which applicant intends as the invention. Applicants argue that derivatives are defined on page 16 of the specification, however, as set forth supra, limitations from the specification are not read into the claims. Moreover, applicants argue that one of skill in the art would known what a pectin derivative is. The examiner disagrees, without defining what is intended by a derivative, one would not be able to determine the metes and bounds of the claim.

The phrase "delivering at least 5% of a polysaccharide" in all instances, such as claim 38, (and in all percentages such as in claims 113-115) is indefinite. It is unclear if applicants intend to deliver at least 5% of a polysaccharide, i.e., 1 sugar residue of a polysaccharide which is a 20-mer (5% of the 20-mer), or if they intend to deliver 5% of the total of the polysaccharides administered.

Claim 58 is indefinite wherein the claim intends to administer the composition of claim 43, however, it is noted that claim 43 is not drawn to a composition, but rather a glycosaminoglycan. Correction is required.

The term "rapidly" in claims 59 and 73 are relative terms which render the claims indefinite, and therefor the rejection is maintained for reasons of record. The terms are not defined by the claim, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Applicants argue that the terms are definite, and that the requisite timeframes are set forth in the claims. However, the examiner disagrees. The claims are drawn to "rapidly delivering a polysaccharide" wherein "a peak plasma concentration is reached within two hours", or "at least 5% is delivered to the blood within 1 hour". These are not seen as definitions for "rapidly delivering a polysaccharide", but defining at what time peak concentration is observed or where at least 5% is found in the blood.

The phrase "heparin-like glycosaminoglycan" in claims 82, 89, and 90 is a relative term which renders the claims indefinite, and therefor the rejection is maintained for reasons of record. The term is not defined by the claims, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. How must another compound be like heparin to be considered "heparin-like"? Must it have the same properties, be the same size, have the same functional groups, comprise the same linking groups? Applicants argue that the term is defined in the specification, however, as set forth supra, the examiner will not read these limitations into the claims. Applicants are encouraged to incorporate into the claims that which there is support founded in the specification.

Claim 91 is indefinite wherein the claim is drawn to a kit comprising an inhalation apparatus, a polysaccharide, and a detection system. It is unclear as to what exactly a "detection system" is. There is nothing in the claim about detecting anything, and it is unclear as to what the "detection system" is included in the kit for. Applicant's arguing that the term is defined in the specification will not substitute for defining the same in the claim.

Claims 126 and 150 are drawn to compositions including "a polymer to effect slow release of the glycosaminoglycan", which is seen to be missing a critical element. The claims fail to particularly point out the identity of the polymer to be used in the composition instantly claimed. The current claim language is drawn to a composition which is not described structurally/formulaically/nomenclatorially; but rather by the various agents' mode of action, function or effect requisite to an activity produced by the composition. The claim is missing the critical element, which is the particular or distinct identity of the polymer to be used in the composition. Defining the polymer structurally, formulaically, or nomenclatorially would be a more preferable way to define the subject matter instead of the current functional description. Moreover, it is unclear as to what "effect slow release" is, as this could increase or decrease the slow release of the glycosaminoglycan.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by

raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 196 recites the broad recitation "the polysaccharide is a glycosaminoglycan", and the claim also recites "and the glycosaminoglycan is selected from the group consisting of..." which is the narrower statement of the range/limitation.

All claims which depend from an indefinite claim are also indefinite. ***Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).***

Claim Rejections - 35 USC § 102

Claims 38, 42, 43, 58, 59, 73, 79, 89, 90-91, 99, 113-119, 121-123, 125-126, 130-134, 141-147, 149-151, 153-154, 158-163, 168-177, 184-198, and 203 are rejected under 35 U.S.C. 102(b) as being anticipated by Illum et al. (WO 97/35562).

The claims of the instant application are drawn to various compositions and methods comprising the use of polysaccharides and/or glycosaminoglycans in formulated or unformulated form wherein the polysaccharides are from 1-500 microns in diameter and are delivered into the lung to obtain rapid release.

Illum et al. discloses microspheres which are made from polysaccharides wherein the polysaccharides can be any of amylodextrin, amylopectin, hydroxyethylstarch, carboxymethylcellulose... or polyglucosamine (page 11, lines 25-30). Polyglucosamines are known in the art to be polysaccharides having glucose monomer units with amine functionality in the polysaccharide backbone. Typical polyglucosamines include, for example, chitin, chitosan, and polyglucosaminoglycans which are copolymers of N-acetylglucosamine and various glycan sugars, e.g., hyaluronic acid, chondroitin, heparin, keratan and dermatan (as evidenced by Gruber, US Patent 5,597,811). Illum teaches that their polysaccharide microspheres should be of an aerodynamic diameter of between 1-10 microns (page 13, lines 1-4) and that various modifications may be made to provide for delayed release (i.e., a formulated particle) (page 12, lines 5-11). Illum disclose that their particles can provide rapid release, wherein about 80% of the drug is released just after delivery (within 5 minutes) (page 12, lines 13-17). Claim 6 of Illum discloses low molecular weight heparin as a pharmacological agent in their composition. Illum also discloses that additional agents can be included into their microspheres, such as proteins (page 13). Additionally, since both the instant application and Illum disclose various kits, the kits as claimed in the instant application are seen to be anticipated by Illum as the composition of Illum is disclosed as being useful for pulmonary delivery of agents, wherein any suitable dry powder device may be used for delivery (page 14, lines 7-13).

Illum et al. disclose a polysaccharide system which comprises microspheres of polysaccharides in overlapping size, which are made by a one step process of spray drying a drug and a polysaccharide (the drug can be low molecular weight heparin), thus providing an unformulated polysaccharide. Moreover, Illum disclose alternative embodiments in which the

microspheres can be formulated, i.e., for delayed release. Illum disclose their microspheres as being utilized for the pulmonary delivery of drugs wherein a rapid release of the drug is obtained. Illum disclose microspheres having from 1% drug to more than 50% (page 11, lines 1-9). The disclosure of a rapid release (within 5 minutes) is seen to show that the peak concentration would additionally occur rapidly. It is noted, that while Illum is silent to their microspheres' tap density, the examiner believes them to be overlapping with those of the instant application, as the rest of the properties of the compositions are overlapping. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claims 1-3, 5, 8, 11-12, 14-32, and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Illum et al. (WO 97/35562).

The claims are drawn to various methods of treatment or methods for producing therapeutic effects wherein an unformulated dry polysaccharide particle having a mean geometric diameter of 1-500 microns is administered. The polysaccharides can be low molecular weight heparin, and the disorders treated are any number of various disorders known to be treated by polysaccharides, or various subjects which are at risk of contracting various diseases.

Illum et al. disclose compositions comprising unformulated polysaccharides as microspheres having diameters of 1-10 microns (see above). Moreover, Illum disclose delivering the same to the pulmonary cavity via dry powder devices. The fact that Illum discloses these microspheres and delivering the same to the pulmonary cavity inherently discloses methods of

treatment, and methods of producing therapeutic effects, as the same population are treated with the same compositions, thus the disclosure of Illum is seen to anticipate the methods of treatment as set forth in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-38, 42-43, 58-59, 73, 79, 82, 89-91, 99, and 113-203 are rejected under 35 U.S.C. 103(a) as being unpatentable over Illum et al. (WO 97/35562) as set forth supra.

The claims of the instant application are drawn to the methods and compositions as set forth supra, additionally wherein the particles are above 10 microns (or above 30 microns) and wherein the polysaccharide is various heparins, such as biotechnology derived heparin.

Illum et al. disclose various compositions and methods as set forth supra, what is not taught is the use of the various heparins, nor to use particles above 30 microns in size.

It would have been obvious to one of ordinary skill in the art at the time of the invention to make various microspheres out of other polysaccharides, such as biotechnology derived heparin, because Illum teaches that the compositions can be prepared using any different soluble polysaccharide (page 11, lines 25-29). One would be motivated to use various polysaccharides because Illum teaches that any can be used. Moreover, the various size modifications to the particles are seen to be obvious in light of the Illum reference. Moreover, selection of particle size is not a patentable modification in the absence of unobvious results. See ***In re Rose, 105 USPQ 237 (CCPA 1955).***

The claims of the instant application are seen to be anticipated by, or in the alternative, obvious in light of the Illum reference.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
May 24, 2004

James O. Wilson
Supervisory Patent Examiner
Art Unit 1623